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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/674,280	12/21/2000	Michinobu Nakamura	197748US0PCT	5123
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22850 7590 10/21/2002

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/21/2002 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,280

Applicant(s)

Nakamura et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 8, 14, 15, and 22-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 14, 15, and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/14/2002 has been entered.

Status of claims

Claims 7, 8, 14, 15 and 22-26 as amended are pending and under examination. [Paper No. 12 filed 5/14/2002].

Claims 1-6 were canceled by applicants. [Paper No. 9 filed 10/29/2001].

Claims 9-13 and 16-21 were canceled by applicants [Paper No. 12 filed 5/14/2002].

Claim Rejections - 35 U.S.C. § 112

Claims 7, 8, 14, 15 and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because the difference, if any, between two microbial compositions such as "koji mold" and "fungal culture" is uncertain as claimed. Both microbial compositions comprise microorganisms belonging to the species of *Aspergillus oryzae*. However, it is uncertain whether there are some differences between microbial compositions with *Aspergillus*

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oryzae before and after cultivation in “submerged culture fermenter-type reaction vessel”. In the lack of clear differences which might be induced while conducting cultivation in “submerged culture fermenter-type reaction vessel”, the step (1) is interpreted as a conventional preparation of fungal inoculum.

Claim 7 is indefinite because it repeats phrases “said” vegetable protein and “said” fungal culture twice (see steps 2 and 3) and thus, the antecedent basis for “said” compositions and the sequence of the steps is uncertain as claimed.

Claim 14 is indefinite with respect to step of “substantially removing air bubbles” because it is uncertain how much is intended by “substantially” and what is a protocol of application which removes air bubbles before sterilization .

Claims 22 is indefinite because it is not particularly clear whether the claimed temperature range from 25°C to 38 °C is intended as a substep which occurs before enzymatic hydrolysis of step (3) in the method of claim 7 or whether the claimed temperature range from 25°C to 38 °C is intended to limit first temperature range from 15°C to 39 °C in the method of claim 1.

Claims 23 and 24 are rendered indefinite by the phrase “completed” because it is uncertain what would be an indication of the “completed” process. How long does the hydrolysis last? When it is “completed” or terminated? The metes and bounds of the claimed method can not be determined. (Claims 23 and 24 are substantial duplicates.)

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Claims 25 and 26 are indefinite for the same reasons as for claims 23 and 24 with respect to the phrase "completion". It is unclear when temperature "is shifted... so that a ratio of reducing sugars" would reach a particular level as claimed. What are criteria of the intended "completion"? Is "completion" is a time period? Is "completion" is amount of reducing sugars? When does the shift of temperature occur? When does the process stop? The metes and bounds of the claimed method can not be determined. Also the same shift in temperature appear to achieve different ration of reducing sugars. It is uncertain how this is intended to be achieved.

Claims 25 and 27 are indefinite and confusing in the yield of "a ratio". Is "the" ratio intended?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/28853 [N] in view of US 4,808,419 [D].

The claims are directed to a method for producing hydrolyzed protein from vegetable protein material wherein the method comprises step of preparing a fungal koji mold culture inoculum, step of mixing the fungal koji mold culture inoculum with a vegetable protein

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material, step of conducting enzymatic hydrolysis at first temperature of about 15-39°C or about 25-38°C with aeration and agitation and then at second temperature of about 40-60°C or of about 41-50°C . The claimed step of preparing a fungal koji mold culture inoculum is conducted in a “submerged culture fermenter-type reaction vessel”. The final hydrolyzed protein contains 5% and less of reducing sugars. Some claims are further drawn to the use of vegetable protein material such as wheat gluten or de-fatted soybean.

WO 95/28853 [N] discloses a method for producing hydrolyzed protein or a seasoning sauce (see abstract or see page 9, par. 2 and par. 4 or see page 11) wherein the method comprises step of preparing a fungal koji mold culture inoculum comprising *Aspergillus oryzae* spore suspension, step of mixing the fungal koji mold culture inoculum with a vegetable protein material such as wheat gluten, step of conducting enzymatic hydrolysis at first temperature of about 30 °C with aeration and agitation or mixing and then at second temperature of about 40-45°C. The cited reference suggests the use of defatted soybean (page 1, par. 1) in a method for producing hydrolyzed protein. The cited method encompasses the use of a container or a fermenter for liquid or submerged fermentation reaction or enzymatic hydrolysis by teaching the use of a liquefied gluten suspension within the container wherein it is further mixed with fungal koji mold inoculum (page 9, par. 2, line 1, 3 and 14). The fungal koji mold inoculum is prepared from the spore suspension of *Aspergillus oryzae*.

Although the cited patent WO 95/28853 [N] does not clearly discloses concentration of reducing sugars in the final hydrolyzed protein product, theirs amounts are considered to be

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substantially similar, if not identical, to the presently claimed amounts because the identical vegetable materials are subjected to identical two-temperature stage enzymatic koji mold hydrolysis as presently claimed and as disclosed by the cited patent. Thus, the final products would be substantially similar, if not identical, as result of practicing substantially similar protocols of making. Moreover, the cited patent WO 95/28853 [N] clearly teaches making and obtaining a hydrolyzed protein product with a lighter color what is reasonably expected to be due to the lack of reducing sugars which commonly have browning effects (see instant specification page 5, par. 3).

Although the cited patent WO 95/28853 [N] does not clearly disclose the design of container or tray which is used for making a fungal inoculum or a fungal culture, the fungal culture which serves as inoculum and which is used for producing hydrolyzed protein in the method of the cited patent is considered to be substantially similar to the presently claimed fungal culture because it is derived from the identical "koji mold" as claimed and/or from identical spore suspension of *Aspergillus oryzae* as disclosed by applicants (page 24, line 12). The difference between a starting "koji mold" and "a fungal culture" derived from "koji mold" by cultivation in a "submerged culture fermenter-type reaction vessel" can not be determined as claimed and as disclosed by the present invention.

The cited patent US 4,808,419 [D] is relied upon to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis

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including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of WO 95/28853 [N] in “a submerged culture fermenter-type reaction vessel” as intended the presently claimed invention with a reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419 [D], for example, and they are available for fermentation and hydrolysis of vegetable materials including koji fermentation. One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 7, 8 and 22-26 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] in view of US 4,808,419 [D].

The claims are directed to a method for producing hydrolyzed protein from vegetable protein material wherein the method comprises step of preparing a fungal koji mold culture inoculum, step of mixing the fungal koji mold culture inoculum with a vegetable protein

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material, step of conducting enzymatic hydrolysis at first temperature of about 15-39°C or about 25-38°C with aeration and agitation and then at second temperature of about 40-60°C or of about 41-50°C . The claimed step of preparing a fungal koji mold culture inoculum is conducted in a “submerged culture fermenter-type reaction vessel”. The final hydrolyzed protein contains 5% and less of reducing sugars. Some claims are further drawn to the use of vegetable protein material such as wheat gluten or de-fatted soybean.

US 6,045,819 [A] discloses a method for producing hydrolyzed protein from vegetable material wherein the method comprises step of preparing a koji starter or a fungal culture inoculum derived from various koji molds including *Aspergillus oryzae* (col. 10, lines 30-39 and col.11, lines 47-50), mixing the koji starter with a vegetable material such as de-fatted soybeans (col. 9, lines 55-57), step of conducting first stage fermentation at temperature 28-30°C with aeration (col.9, line 60) and conducting second stage fermentation at temperature 30-60°C (col. 10, line 66) or 50°C (col. 11, line 56) or 58 °C (col. 12, line 2). The cited method encompasses the use of a liquid or “submerged culture fermenter-type reaction vessel” by disclosing a device capable to hold fermentation reaction with addition of water into reaction system (col. 11, lines 66-68; col. 8, line 65) in a method for producing hydrolyzed protein. The final hydrolyzed product obtained by two stage temperature fermentation of the cited patent is substantially free from reducing sugars because the cited patent teaches that the glycosidic saccharide originally present in vegetable material are decomposed to an undetectable extend (col. 12, line 21 and line 31).

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In addition, the cited patent US 6,045,819 [A] teaches pre-treatment of vegetable material before enzymatic hydrolysis. The method of the cited patent encompasses step of pulverization of vegetable material prior to fermentation by teaching the use of soy powder or small granules (see col. 9, lines 11-20, for example). The cited method teaches a step of pasteurization or sterilization of vegetable material prior to fermentation by teaching cooking and/or heating soybeans (Fig. 1). The cited method encompasses steps of removing air bubbles from vegetable material prior sterilization or cooking by teaching kneading vegetable material into blocks (col. 9, lines 22-23) or by teaching a cooking step which is reasonably expected to remove at least some air bubbles due to increase of temperature and evaporation. The cited method encompasses sequential steps of dispersing pulverized vegetable material in hot water, removing air bubbles and sterilizing by teaching cooking of vegetable material prior to enzymatic fermentation with koji mold fungal culture.

The method of the cited patent US 6,045,819 [A] is substantially similar the claimed method because it comprises identical steps drawn to the use of two temperature stage enzymatic hydrolysis of identical vegetable protein material with substantially identical fungal culture which is a source of enzyme required for hydrolysis such as koji mold fungus *Aspergillus oryzae* wherein the method results in the possession of identical hydrolyzed protein product which is substantially free from reducing sugars.

The cited patent US 6,045,819 [A] is silent with regard to a particular design for a fermenter reaction vessel.

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But the cited patent US 4,808,419 [D] is relied upon to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the method of US 6,045,819 [A] in “a submerged culture fermenter-type reaction vessel” as intended the presently claimed invention with a reasonable expectation of success in producing hydrolyzed proteins with decreased amounts of reducing sugars because various fermenters including submerged culture fermenter-type reaction vessel are known in the prior art as demonstrated by US 4,808,419 [D], for example, and they are available for fermentation and hydrolysis of vegetable materials including koji fermentation. One of skill in the art is free to choose a fermenter suitable for koji fermentation which is known and/or available on a market. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 7, 8, 14, 15 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,045,819 [A] and WO 95/28853 [N] in view of US 5,888,561 [C] and US 4,808,419 [D].

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The claims 7, 8 and 22-26 as explained above. Claims 14 and 15 are further drawn to pre-treatment of vegetable protein material by steps of pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material prior to fungal fermentation.

The cited references US 6,045,819 [A] and WO 95/28853 [N] are relied upon as explained above. They both teach methods for producing hydrolyzed vegetable protein material having substantially decreased amounts of reducing sugars by applying two temperature stage fermentation with koji mold fungal culture.

WO 95/28853 [N] is silent with regard to pre-treatment of vegetable material prior to fermentation. But US 6,045,819 [A] encompasses steps of pulverizing, dispersing, removing air bubbles and sterilizing the vegetable protein material prior to fungal fermentation as explained above. Thus, US 6,045,819 clearly teaches and suggests application of pre-treatment steps in the method for producing hydrolyzed protein material.

Further, the cited US 5,888,561 is relied upon to demonstrate that pre-treatment of vegetable material by pulverization and sterilization prior to koji mold fermentation is a conventional procedure (example 1) in the method for producing hydrolyzed proteins characterized by decreased amounts of reducing sugars (col. 1, line 63-66). In addition, the cited patent US 5,888,561 also discloses a step removing air bubbles from the pulverized and dispersed vegetable material prior to sterilization by teaching that soaked vegetable extrudates were subjected to vacuum before pasteurization (col. 3, line 48).

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Further, the cited patent US 4,808,419 [D] is relied upon as explained above to demonstrate that fermenters for submerged or semi-solid fermentation of vegetable materials by microbial enzymatic hydrolysis including the use of koji preparation derived from *Aspergillus oryzae* are known in the art and commercially available (see abstract or Fig. 1 or col. 10, line 30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to subject the vegetable material to a pre-treatment prior to enzymatic fermentation in the methods of US 6,045,819 [A] or WO 95/28853 [N] as suggested by US 6,045,819 [A] with a reasonable expectation of success in producing hydrolyzed proteins because pre-treatment including pulverization, dispersion, removing of air bubbles and sterilization are conventional procedures in the methods for koji mold fermentations as evidenced by US 5,888,561. Further, with respect to pulverization step, it is considered to be a choice of experimental design to pulverize the vegetable material to various sizes including that of 300 μm or less as encompassed by the claimed method in the absence of evidence to the contrary.

Moreover, the instant application does not regard the importance of size being 300 μm or less and it teaches alternative use of particle sizes more than 300 μm (See specification page 11, par. 3). The comparative example in the applicants' specification is directed to the advantage of two temperature stage fermentation when compared to one temperature stage fermentation in a method for making hydrolyzed product with decreased amount of reducing sugars (see pages 25-27 and tables 1-2) rather than to criticality of a specific protocol of pre-treatment of vegetable material prior to koji fermentation. One of skill in the art is free to choose a fermenter suitable

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for koji fermentation which is known and/or available on a market {US 4,808,419 [D]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No claims are allowed.

Response to Arguments

Applicants' amendments and arguments filed 10/29/2001 have been fully considered but they are not persuasive for the reasons below.

With regard to the cited patent WO 95/28853 [N] applicants argue that it does not teach the use of a "submerged culture fermenter-type reaction vessel" (response page 3, last par.). However, since the differences between starting "koji mold" and "a fungal culture" derived from "koji mold" by cultivation in a "submerged culture fermenter-type reaction vessel" are not clearly delineated, this argument does not appear to have persuasive grounds. Thus, the fungal cultures which are made either in a tray or in a "submerged culture fermenter-type reaction vessel" are not at least functionally different because they are both suitable for enzymatic hydrolysis of vegetable material. The present invention does not appear to utilize a specially designed fermenter neither for koji inoculum preparation nor for enzymatic hydrolysis step. And the presently claimed invention does not require to use a "submerged culture fermenter-type reaction vessel" in the step of enzymatic hydrolysis.

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With regard to the method of US '819 (Takebe) applicants argue that one of skill in the art would not recognize the fermenter or "device" for enzymatic fermentation as a "submerged culture fermenter-type reaction vessel" (response page 4, par. 3). However, the present invention does not utilize a specially designed fermenter for koji inoculum preparation or for enzymatic hydrolysis step to support the instant argument and/or to point out the differences which might be intended. Thus, the "device" of the cited patent US '819 (Takebe), which is used for enzymatic fermentation in the presence of water or in aqueous medium wherein the method results in production of identical hydrolyzed protein lacking reducing sugars, is considered to be substantially similar, if not identical, to a "submerged culture fermenter-type reaction vessel" as claimed and as intended by applicants.

Applicants also argue that the cited patent US '819 (Takebe) discloses a decrease and/or fluctuations of temperature during the first temperature stage fermentation (response page 4, last par.). However, the claimed invention allows for the same changes within ranges of about 15-39°C or of about 25-38°C during first temperature stage fermentation with agitation and aeration as it is demonstrated in the process of the cited patent. The use of a "submerged culture fermenter-type reaction vessel" does not necessarily indicate that at least some temperature fluctuations might be avoided when fermenter contents are agitated, aerated or mixed. Moreover, the claimed method does not comprise the use of a "submerged culture fermenter-type reaction vessel" during the step of enzymatic hydrolysis.

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The claim rejection over references US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al. [U] has been withdrawn in the instant office action due to redundancy of teaching drawn to method of making hydrolyzed vegetable protein material with decreased amounts of reducing sugars in the light of the presently claimed invention as amended.

In response to the applicants' request to consider documents cited in the International Search Report (see last response page 5) it is noted that the "A" category documents cited in the International Search Report for PCT/JP99/02171 have been considered by examiner to the extend as provided by applicants.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova, Art Unit 1651

October 11, 2002.


IRENE MARX
PRIMARY EXAMINER